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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,844	04/21/2004	Charles W. Alvord	30392.00	5306
22465	7590	12/14/2004	EXAMINER	
PITTS AND BRITTIAN P C P O BOX 51295 KNOXVILLE, TN 37950-1295			BARTON, JEFFREY THOMAS	
			ART UNIT	PAPER NUMBER
			1753	
DATE MAILED: 12/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/828,844

Applicant(s)

ALVORD ET AL.

Examiner

Jeffrey T. Barton

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 20040916.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

1. Claims 1, 2, 4, 8, 15, 16, 20, 26, 28, and 32 are objected to because of the following informalities: at various places in these claims, "charge particle detector" is recited instead of "charged particle detector". Appropriate correction is required.
2. Claims 9, 21, and 33 are objected to because of the following informalities: they are unclear because of the phrase, "... or the second and the second electrodes." Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 8, 9, 13, 20, 21, 32, 33, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims appear to be directed to the embodiment shown in Figure 8. However, it is not clear how the detector functions here - are there two separate p-n junctions? (indicated at 30' and 110) If so how can it be referred to as a single detector? Is the p-n junction located in Si block 15, directly adjacent the

channel? If so, there is no window between the channel and detector as required in the independent claims. It is not clear how the claims correspond to Figure 8 and the independent claims simultaneously.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 7, 10, 12, 25, 31, 34, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Burns et al.

Regarding claim 1, Burns et al disclose a detector assembly, comprising a base with a microfluidic channel formed in the base allowing fluids to flow therethrough. (Figure 1); a window formed in the base; a solid state charged particle detector supported by the base, wherein the window is positioned between the detector and the channel, and the window has a thickness sufficient to allow beta particles through to be detected. (Fabrication described at Column 31, line 43 - Column 32, line 38; window would comprise thermal SiO<sub>2</sub> and baked photoresist layers described at Column 32, lines 23-32, detector is disclosed as being fabricated beneath the channel at column 32,

lines 5-8) Since the window thickness of the detector is sufficient to allow negative beta particles to pass, it would also allow positrons to pass.

Regarding claim 25, the window means allows the radiation to pass through a thin layer (i.e. 0.2  $\mu\text{m}$  of  $\text{SiO}_2$ /photoresist), while the layers of  $\text{SiN}_x$ /poly Si/ $\text{SiN}_x$  that otherwise surround the channel do not. The thinness of the window increases linear resolution by providing a narrower range of angles from which the particles must come in order to be detected.

Regarding claims 7 and 31, this detector is completely integral with the base, since the entire device is fabricated as a series of solid layers above the wafer in which the detector was fabricated.

Regarding claims 10, 12, 34, and 36, Burns et al disclose the base of their device comprising silicon and polymer. (Column 32, lines 19-32)

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-7, 10-12, 14-19, 22-31, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktorowicz et al in view of Tokita et al and Karmen. The description of Tokita et al is based in part on a partial oral translation.

Regarding claims 1, 14, and 25:

Wiktorowicz et al disclose a microfluidic assembly, comprising a base (Figure 4, plates 120 and 122); and microfluidic channels formed in the base allowing fluids to flow therethrough. (Figure 4, 170; Column 8, lines 6-27) (Column 6, lines 15-19 and 24-26; Column 16, lines 43-49)

Wiktorowicz et al do not explicitly disclose a detector assembly comprising a window of any type formed in the base, or a solid-state charged particle detector supported by the base wherein the window is interpositioned between the charged particle detector and the channel.

Tokita et al disclose a particle detecting assembly comprising a radiation detector (Figures 1 and 2, detectors 5a-5d) supported by a base (Cassette with plates 1a and 1b) that is a multilane electrophoresis cassette similar to that of Wiktorowicz et al, wherein a window is formed in the base (Spacer 3 below slit 10), wherein the window has a thickness sufficient to allow transmission of beta particles from phosphorus-32. (See abstract; Page 315, 2<sup>nd</sup> column, lines 3-15) Since the window thickness of the detector of Tokita et al is sufficient to allow negative beta particles to pass, it would also allow positrons to pass.

Tokita et al do not explicitly disclose using a solid-state particle detector.

Karmen teaches the suitability of using solid-state particle detectors in place of other types of radiation detectors. (e.g. Geiger counters, photomultiplier tubes with scintillators, gas detectors) (Column 3, lines 4-12; Column 5, lines 1-55) Typical solid-state detectors (e.g. silicon p-n junction type) would be fully capable of detecting positrons as well as negative beta particles.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wiktorowicz et al by adding a particle detector of the type used by Tokita et al (i.e window/spacer 3, slit 4, detector 5) because it would provide digital data for more facile analysis, compared to the phosphor plates suggested by Wiktorowicz et al in the case of radioactivity detection. (Column 16, lines 46-47) In general, Wiktorowicz et al do not specify any preferred type of detector, instead suggesting a range of suitable types. (Column 16, lines 40-56)

It would further have been obvious to modify the combination of Wiktorowicz et al and Tokita et al by specifically using solid state radiation detectors, as taught by Karmen, because it would provide a rugged system with high sensitivity and minimal complexity.

The limitation in the preamble, "for quantifying concentration of positron emitters" and recitation of "positron emitters" in defining the thickness of the window are not considered to limit the scope of the claim such that positron emitters must be present in the device, as it merely involves the intended use of the device. "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Relevant to claim 14, collimation means are disclosed (Slit 4) by Tokita et al and would be present and proximate the microfluidic channel in the combination described above.



Relevant to claim 25, the window (Spacer 3) of Tokita et al increases the resolution of the device by allowing the radiation to pass, as opposed to the surrounding area.

Addressing the dependent claims:

Relevant to claims 2, 15, and 26, Tokita et al disclose a portion of the base adjacent the window and supporting the detector having a thickness sufficient to attenuate the beta particles. (Thick portion of plate 1a adjacent the window, e.g. Figure 2a)

Relevant to claims 3, 4, 16, 27, and 28, Tokita et al disclose a collimation well disposed in the base between the window and the detector. (Figure 2a, slit 4)

Relevant to claims 5, 17, and 29, Tokita et al disclose the collimation well comprising a continuous side wall defined by the base (Figure 1b, slit 4 illustrated as extending to the plate 1a)

Relevant to claims 6, 18, and 30, Tokita et al disclose the well having a depth sufficient to collimate the beta particles, enabling the detector to delineate between the particles passing through the window and those attenuated by the base. (The glass base of Tokita et al is not disclosed as allowing particles to pass through, therefore, delineation of the signals is achieved)

Relevant to claims 7, 19, and 31, it would be necessary to secure the detector of Tokita et al and the base of the cassette together in fixed relationship for reliable operability of the combined device as described above. For instance, spacer 3 (a part

of the detector assembly) would need to be secured into opening within the cassette for casting of the gel. As such, the detector and base can be referred to as integral.

In incorporating the detector of Tokita et al into the cassette of Wiktorowicz as described above, these aspects of the detector would necessarily be incorporated into the combination.

Relevant to claims 10-12, 22-24, and 34-36, Wiktorowicz et al disclose glass or plastic plates. (Column 6, lines 15-26)

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

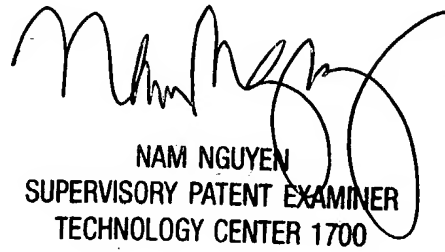
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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JTB  
December 9, 2004



NAM NGUYEN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700